UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	)	**MDL No. 1456** **Master File No. 01-12257-PBS** **Subcategory Case No. 06-11337**
	)	**Judge Patti B. Saris**
THIS DOCUMENT RELATES TO: *State of California, ex rel. Ven-A-Care of the Florida Keys, Inc. v. Abbott Laboratories, Inc., et al.* Case No: 1:03-cv-11226-PBS	)	**Magistrate Judge** **Marianne B. Bowler**

PLAINTIFFS' MEMORANDUM IN OPPOSITION TO DEFENDANT MYLAN'S MOTION FOR PARTIAL SUMMARY JUDGMENT

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Statutes

Other Authorities

Rules

INTRODUCTION

Pursuant to Fed. R. Civ. P. 56 and Local Rule 56.1, Plaintiffs, the State of California and Ven-A-Care of the Florida Keys, Inc. ("Plaintiffs"), submit their Memorandum in Opposition to Mylan Pharmaceuticals, Inc. and Mylan Laboratories, Inc.'s ("Mylan's") Motion for Partial Summary Judgment. Plaintiffs incorporate by reference their Memorandum in Opposition to the Defendants' Joint Motion for Summary Judgment, their Response to the Defendants' Joint Statement of Undisputed Material Facts, their Response to Mylan's Statement of Undisputed Material Facts in Support of Mylan's Motion for Partial Summary Judgment, and their Statement of Additional Undisputed Material Facts in Opposition to Mylan's Motion for Partial Summary Judgment.

Mylan moves for partial summary judgment on five separate grounds, none of which have merit. First, Mylan argues that the statute of limitations bars Plaintiffs' claims prior to August 1999, as California "discovered" the false claims violations by July 1998. However, absent "discovery," California's False Claims Act ("CA FCA") allows claims that are filed within 10 years after the date on which the violation is committed. Mylan has not established that California "discovered" the alleged conduct prior to August 1999.

Second, citing the findings from two Myers and Stauffer reports and comparing them to Medi-Cal[1] claims data from 2000, Mylan argues that California did not "overpay" for Mylan's products between 1994 and 2004, but only made "modest dollar payments" above the provider's cost. This, it argues, was consistent with California's obligations under Ninth Circuit precedent. However, as shown herein, the data does not support Mylan's argument. Instead, Mylan has selectively cited 7 NDCs which are not representative, or otherwise indicative, of dollar payment margins during the subject time period. Further, as set forth more fully in Plaintiffs' Opposition

[1] California's Medicaid program is known as "Medi-Cal."

to Defendants' Joint Brief, the argument that California chose to reimburse pharmacists based on grossly inflated AWPs in order to be consistent with its obligations under Ninth Circuit precedent is not supported by the evidence, or the holdings of the Ninth Circuit.

Third, Mylan argues that Plaintiffs' claims relating to the drugs clorazepate and lorazepam are barred by the *res judicata* effect of California's 2001 antitrust settlement with Mylan relating to Mylan's attempt to monopolize the Active Pharmaceutical Ingredient ("API") for its drug products, as alleged in the antitrust case. As set forth more fully below, Plaintiffs' present claims are not barred because they do not arise from the same common nucleus of operative facts as the claims that were settled in the antitrust case. In summary, the antitrust case claims related to Mylan's attempt to raise actual transaction prices to customers through the use of a monopoly. The current case involves the use of false reported prices having no correlation whatsoever to real prices, and, in any event, this Court has already rejected the same argument in a parallel case.

Fourth, Mylan argues that the current claims were released as part of the antitrust case settlement. As discussed below, this contention is inaccurate because the 2001 Settlement Agreement specifically limited the claims released to the specific conduct alleged in the antitrust complaint. The release does not include any reference to CA FCA claims and none of the allegations of the antitrust complaint relate to publication of false AWP prices in the price compendia.

Finally, Mylan argues that the entity Mylan, Inc., formerly known as Mylan Laboratories, Inc., is not a proper party to this lawsuit and that Plaintiffs should have sued only its wholly-owned subsidiary, Mylan Pharmaceutical, Inc. As set forth below, and in Plaintiffs' Response to Mylan's Statement of Undisputed Material Facts ("CA Resp. Mylan SOF") at paragraphs 35

through 38, there is a genuine issue of material fact as to whether Mylan, Inc., formerly Mylan Laboratories, Inc., manufactured, marketed and sold the drugs at issue in this case during the relevant time period. There is also a genuine issue of material fact as to whether this entity and its predecessor controlled the actions of its wholly-owned subsidiary corporation, Mylan Pharmaceuticals, Inc.

For these reasons, Defendant Mylan has failed to carry its burden of showing that there are no genuine issues of material fact for trial and that it is entitled to summary judgment as to any of Plaintiffs' claims.

I. DEFENDANT MYLAN IS NOT ENTITLED TO PARTIAL SUMMARY JUDGMENT ON THE BASIS OF THE STATUTE OF LIMITATIONS

A. Absent "Discovery" by the State Attorney General, a CA FCA Claim Involving State Funds Must Be Filed No More Than 10 Years After the Date on which the Violation Is Committed.

To be timely, a claim under the CA FCA (CAL. GOV'T CODE § 12650 *et seq.*) must be filed within three years "after the date of discovery by the official of the state or political subdivision charged with responsibility to act in the circumstances or, in any event, no more than 10 years after the date on which the violation of Section 12651 is committed." CAL. GOV'T CODE § 12654(a); *Debro v. Los Angeles Raiders*, 92 Cal. App. 4th 940, 947 (2001). In other words, absent "discovery" of the violation at issue, a CA FCA claim is timely if filed within 10 years after the date such violation occurred.[2]

[2] Under the continuing accrual doctrine, "[w]hen an obligation or liability arises on a recurring basis, a cause of action accrues each time a wrongful act occurs, triggering a new limitations period. [Citation.] The continuing accrual rule has been applied in a variety of actions involving the obligation to make periodic payments under California statutes or regulations." *Hogar Dulce Hogar v. Community Development Commission*, 110 Cal. App. 4th 1288, 1295 (2003) (citing inter alia, *Howard Jarvis Taxpayers Assn. v. City of La Habra*, 25 Cal. 4th 809, 818-825 (2001) (doctrine applied to action involving taxes). In the present case, each false AWP report gave rise to a new claim.

"The purpose of the [CA FCA] is to protect the public treasury and the taxpayer. [Citation.] Accordingly, the act must be construed broadly to give the widest possible coverage and effect to the prohibitions and remedies it provides. [Citation.]" *County of Kern v. Sparks*, 149 Cal. App. 4th 11, 17 (2007).

Although the CA FCA was modeled after the federal False Claims Act (31 U.S.C. § 3729 *et seq*.), *see Rothschild v. Tyco Internat. (US), Inc.*, 83 Cal. App. 4th 488, 494 (2000)), "the language of the federal statute of limitations differs significantly" from that of Section 12654(a). *State of California ex rel. Hindin v. Hewlett-Packard Co.* ("*Hindin*"), 153 Cal. App. 4th 307, 318 (2007); *Debro*, 92 Cal. App. 4th at 949. For example, under the federal statute, the limitations period begins when material facts were "known or reasonably should have been known" (31 U.S.C. § 3731(b)(2)), whereas the California statute of limitations commences upon "discovery." *Hindin*, 153 Cal. App. 4th at 318; *Debro*, 92 Cal. App. 4th at 949; CAL. GOV'T CODE § 12654(a). California courts, therefore, have found federal cases interpreting federal False Claims Act language to be unpersuasive in interpreting the CA FCA's limitations provisions. *Hindin*, 153 Cal. App. 4th at 318; *Debro*, 92 Cal. App. 4th at 949.

Under the CA FCA, "discovery" occurs when the responsible government official "either knows of the false claim or knows of facts which would lead a reasonably prudent person to suspect it." *Debro*, 92 Cal. App. 4th at 953. The "plain and commonsense" interpretation of section 12654 is that the limitations period begins on "the date of discovery" by a state official such as the Attorney General, not the private qui tam plaintiff. *Hindin*, 153 Cal. App. 4th at 314; *see* CAL. GOV'T CODE § 12654(a). Accordingly, for purposes of the instant motion, this Court must consider, in a manner consistent with California courts' interpretations of Section 12654, the extent and timing of the information known to "the Attorney General, who has responsibility

to act to protect the public fisc from false claims." *See Hindin*, 153 Cal. App. 4th at 315; *accord*, *id.* at 319 (examining when the Attorney General was aware of the claim); *see also, Debro*, 92 Cal. App. 4th at 951.

In the present case, as set forth below, there is no evidence to establish as a matter of law that, prior to August 1999, California knew—or knew facts which would have led a reasonably prudent person to suspect—that among the more than 550 generic drug manufacturers whose products were reimbursed by Medi-Cal, Mylan was falsely reporting the AWPs for the particular drugs at issue in this action. Absent such "discovery" within the meaning of Section 12654(a), the State's claims against Mylan for conduct that occurred prior to August 1999 cannot be barred by the statute of limitations.

B. Defendant Mylan Has Not Irrefutably Established That California "Discovered" the Alleged Conduct Prior to August 1999.

"Summary judgment is not appropriate unless only one reasonable inference can be drawn from undisputed facts." *Cleveland v. Internet Specialties West, Inc.* ("*Cleveland*"), 171 Cal. App. 4th 24, 31 (2009); *accord, Betz v. Trainer Wortham & Co.*, 519 F.3d 863, 871-72 (9th Cir. 2008) ("Summary judgment is appropriate only when uncontroverted evidence irrefutably demonstrates plaintiff discovered or should have discovered the fraudulent conduct."); *see also, Celotex Corp. v. Catrett*, 477 U.S. 317, 322-23 (1986) (Summary judgment is proper only where there is "no genuine issue as to any material fact.").

The statute of limitations provides an affirmative defense for which the defendant bears the burden of proof. *Norgart v. Upjohn Co.* ("*Norgart*"), 21 Cal. 4th 383, 396 (1999).

Only two items of evidence are offered by Mylan to support its statute of limitations defense: (1) the 1996 HHS-OIG publication entitled "Review of Pharmacy Acquisition Costs for Drugs Reimbursed under the Medicaid Prescription Drug Program of the California Department

of Health Services," and (2) the July 1998 *qui tam* complaint in this action. (Mylan's Summary Judgment Brief ("Mylan SJ Br.") at 2-5, referring to Defendants' Joint Statement of Undisputed Material Facts ("Defs. Jt. SOF") ¶¶ 32, 60-63.) Neither document supports Mylan's position.

At best, the HHS-OIG publication revealed that some providers could sometimes obtain some generic prescription drugs at a cost far less than the reported AWPs, resulting in an average pharmacist invoice price for generic drugs at 41.5 percent below AWP. The publication neither affirmatively averred nor compelled the conclusion that any particular manufacturer had engaged in fraudulent conduct or that any particular drug's price had been fraudulently inflated. It made no specific reference to Mylan or to any of the drugs it manufactured – let alone any of the subject drugs at issue herein. Further, it neither revealed nor reasonably suggested that the reported AWPs of Mylan's subject drugs were grossly inflated and unrelated to actual market prices. (CA Resp. Defs. SOF ¶¶ 29-32.)

Similarly, while the 1998 *qui tam* complaint alerted the Attorney General to conduct of particular pharmaceutical manufacturers and of specific drug products, it did not identify Mylan or any of the drugs it manufactured. (CA Resp. Defs. SOF ¶¶ 60-63.)

Although the responsible public official need not know "every detail or determine the particular legal theory the plaintiff would later assert" to trigger the statute of limitations, *Debro*, 92 Cal. App. 4th at 955, Mylan has not presented any facts that would irrefutably establish that the Attorney General either knew that Mylan falsely reported its AWPs or knew "facts which would lead a reasonably prudent person to suspect it." *See Debro*, 92 Cal. App. 4th at 953. The record in this case therefore does not permit judgment as a matter of law, as it presents genuine issues of material fact regarding the extent and timing of information available to the Attorney General concerning each drug at issue in this action, and whether such information was sufficient

to trigger the statute of limitations under California law. Summary judgment on this ground is therefore precluded.

C. Defendant's Reliance on *In re Pharmaceutical Indus. Average Wholesale Price Litig.*, 491 F. Supp. 2d 20 (D. Mass. 2007) is Misplaced.

Defendant Mylan suggests that this Court should find the statute of limitations bars California's claims prior to 1999, just as it held the Massachusetts third-party payors' pre-December 1997 claims to be untimely in *In re Pharmaceutical Indus. Average Wholesale Price Litig.*, 491 F. Supp. 2d 20 (D. Mass. 2007). However, this Court's determinations in the 2007 case followed a 20-day bench trial that included testimony from nearly 40 witnesses, *id.* at 30, while the instant matter is still at the summary judgment stage. Indeed, on summary judgment motions in a subsequent Massachusetts drug-pricing case against Mylan, this Court declined to determine the triggering event(s) of the limitations period, stating, "[t]he Court will have to address statute of limitations—what the government should have known, and when it should have known it—drug-by-drug." *Massachusetts v. Mylan Labs.* ("*Mylan Labs*"), 608 F. Supp. 2d 127, 160 (D. Mass. 2008).

Further, in *In re Pharm. Indus. Average Wholesale Price Litig.*, 491 F. Supp. 2d 20, this Court explained,

> When Congress passed the Balanced Budget Act of 1997, it put third party payors on inquiry notice that many AWPs were not true prices paid by physicians and pharmacies to acquire the pharmaceuticals. The class period ends in 2003 when Congress passed the Medicare statute setting new reimbursement benchmarks.

Id. at 31-32. This Court made its findings, however, upon applying Massachusetts law, specifically a statute regulating private business practices[3], *see id.* at 75-76, not false claims act

[3] "[T]he purpose of [Mass. Gen. Laws] Chapter 93A [was] to 'encourage more equitable behavior in the marketplace and impose liability on persons seeking to profit from unfair practices' . . ." *In re Pharm. Indus. Average Wholesale Price Litig.*, 582 F.3d 156, 194 (1st Cir. 2009); *see also, Purity Supreme, Inc. v. Attorney*

violations, *see id.* at 29. In contrast, "[t]he ultimate purpose of the [CA FCA] is to protect the public fisc." *State of California v. Altus Finance* ("*Altus*"), 36 Cal. 4th 1284, 1296-97 (2006). *See Levine v. Weis*, 68 Cal. App. 4th 758, 764-65 (1998) (distinguishing California Unfair Practices Act and Cartwright Act cases from CA FCA cases), disapproved on other grounds in *Wells v. One2One Learning Foundation*, 39 Cal. 4th 1164, 1197 (2006). Given its clear public purpose, *see Pulcifer v. County of Alameda*, 29 Cal. 2d 258, 262 (1946), which was "'obviously . . . to *prevent fraud on the public treasury*, [California Government Code] section 12653 plainly should be given the broadest possible construction consistent with that purpose.'" *Altus*, 36 Cal. 4th at 1299 (emphasis in original) (quoting *Southern Cal. Rapid Transit Dist. v. Superior Court*, 30 Cal. App. 4th 713, 725 (1994)).

Finally and most significantly, the statute of limitations issue in the 2007 case concerned whether the plaintiffs were entitled to tolling of a concededly-expired limitations period—a showing for which the plaintiffs bore the burden. *See In re Pharmaceutical Indus. Average Wholesale Price* Litig., 491 F. Supp. 2d at 75-76 (citing *Saenger Org., Inc. v. Nationwide Ins. Licensing Assocs., Inc.*, 119 F.3d 55, 65 (1st Cir. 1997)).

In contrast, the burden is on defendants in this action to affirmatively establish a statute of limitations defense. *Norgart*, 21 Cal. 4th at 396; *see also*, *United States v. Carter*, 906 F.2d 1375, 1378 (9th Cir. 1990). "Resolution of the statute of limitations issue is normally a question of fact." *Fox v. Ethicon Endo-Surgery, Inc.*, 35 Cal. 4th 797, 810 (2005); *accord*, *In re Lupron Mktg. & Sales Practices Litig.*, 295 F. Supp. 2d 148, 183 (D. Mass. 2003) ("Whether a plaintiff knew or should have known of an injury so as to trigger the running of a statute of limitations is, with rare exception, a jury issue."). Likewise, a determination of whether reasonable diligence

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General, 380 Mass. 762, 776, 407 N.E.2d 297 (Mass. 1980) (quoting *Lowell Gas Co. v. Attorney General*, 377 Mass. 37, 51, 385 N.E.2d 240 (Mass. 1979)).

was exercised by a plaintiff in discovering a violation "is a question of fact for the court or jury to decide." *Cleveland*, 171 Cal. App. 4th at 31, internal quotation marks and citations omitted.

This case does not present a "rare exception" to the general rule. Mylan has not presented undisputed facts which would irrefutably establish, drug-by-drug, that the Attorney General either knew that Mylan falsely reported its AWPs, or knew "facts which would lead a reasonably prudent person to suspect" such false reporting. *See Debro*, 92 Cal. App. 4th at 953. Because, as discussed above, genuine issues of material fact remain as to the extent, the timing, and the sufficiency of the information available to the Attorney General concerning each drug at issue in this action, summary judgment on the basis of the defendant's affirmative statute of limitations defense must be denied.

II. MYLAN'S PROFFERED EVIDENCE DOES NOT SUPPORT ITS CLAIM THAT CALIFORNIA ONLY PAID MODEST DOLLAR PAYMENTS ABOVE PROVIDERS' COSTS IN ORDER TO COMPLY WITH NINTH CIRCUIT PRECEDENT.

Incorporating by reference an argument set forth in the Defendants' Joint Brief, Mylan asserts that the payments Medi-Cal made for Mylan's drugs were amounts that it "determined were consistent with efficiency, economy and access to quality care, as required by Ninth Circuit precedent." (Mylan SJ Br. 5.) As set forth more fully in Plaintiffs' Opposition to Defendants' Joint Brief, this argument is based on a misapplication of the Ninth Circuit's decision in *Orthopaedic Hospital v. Belshe*, 103 F.3d 1491 (9th Cir. 1997), and on the incredible and unsubstantiated argument that California "decided" to reimburse providers for the subject drugs at substantial spreads—in some instances over 2000%—because the State allegedly deemed such payments necessary. (Defendants' Joint Brief in Support of Motions for Summary Judgment ("Defs. Jt. SJ Br.") at 14-15.)

In an effort to support this argument, Mylan contends that the findings in two Myers and Stauffer reports, when compared with claims data from 2000, confirm that Medi-Cal's total reimbursement payments from 1994 through 2004 were not "overpayments," but resulted in only modest dollar payments above the provider's total cost. (Mylan SJ Br. 5.) Mylan relies on the Declaration of Peter Brase ("Brase Decl."). Mr. Brase, an employee of Defendant's law firm Kelley, Drye & Warren LLP, apparently made certain calculations using California's claims data from 2000 and comparing them with data from the two Myers and Stauffer reports. From this data, Mr. Brase chose seven Mylan NDCs and presented them in his Declaration in an attempt to demonstrate that Medi-Cal's reimbursement payments resulted in only "modest dollar payments" above the provider's total cost.[4] (Brase Decl. 3-7.)

Mylan has failed to establish that the seven NDCs it selected, as well as the time-frame it chose, represent a sample that is indicative of reimbursement payments and dollar margins for drugs between 1994 through 2004. In fact, Mylan has failed to establish that the seven NDCs are even representative of the claims data from 2000. To the contrary, Mylan's selection is *not* representative.

Applying the same comparisons to other NDCs reveals that the findings in the Myers and Stauffer reports, when compared to California's claims data from 2000, actually suggest that Medi-Cal's reimbursement payments were indeed "overpayments," resulting in significant dollar payments above the provider's total cost. (Plaintiffs' Statement of Additional Undisputed Facts ("CA SOAF Mylan") ¶ 2.)

[4] Plaintiffs object to the Declaration of Peter Brase filed in support of defendant Mylan's "Motion for Partial Summary Judgment" on the grounds it is inadmissible under Fed. R. Civ. P. 56(e). The Brase declaration should be excluded because it lacks foundation and contains improper expert opinions by a lay witness. *See Schubert v. Nissan Motor Corporation in U.S.A.*, 148 F.3d 25, 29 (1st Cir. 1998). In the alternative, the Brase declaration should be excluded by the Court because it is an opinion by an expert that has never been "disclosed' as required by Fed. R. Civ. P. 26 (a)(2)(A). Failure to properly disclose the identity of experts is grounds for exclusion under Fed. R. Civ. P. 37(c).

As this comparison demonstrates, the "mega-spreads" between the published prices and actual costs for the generic drugs at issue in this action resulted, in most instances, in "inflated" or "excessive" reimbursement payments to Medi-Cal providers who dispensed these drugs. It is apparent that Mylan merely picked the NDCs which it believed supported the argument that only "modest dollar payments" occurred. For the claims selected for Mr. Brase's Declaration, the average dollar margin was $4.40 and the average margin percent was 30. However, looking at a sample of claims that were not included in the Declaration, the average dollar margin is $41.00 and the average margin percent is 497.

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#	Drug	"Spread" Between Published AWP and Average Actual Acquisition Cost	Actual Medi-Cal Reimbursement Amount per claim (2000)	Provider's Cost	Provider's Dollar Margin or Loss	Provider's Margin or Loss Percent
1	Cimetidine 400mg tablet 00378-0372-05 (subject to a FUL)	3054%	$9.11	$8.74	$0.37	4%
2	Naproxen 500mg tablet 00378-0451-05 (subject to a FUL)	1626%	$14.74	$11.36	$3.38	30%
3	Furosemide 40mg tablet 00378-0216-10 (subject to a FUL)	904%	$6.34	$8.80	($2.46)	-28%
4	Diphenoxylate/Atrophine tablet 00378-0415-10	419%	$17.48	$9.99	$7.49	75%
5	Spirinolctone 25mg tablet 00378-2146-01 (subject to a FUL)	326%	$13.85	$10.13	$3.72	37%
6	Diltiazem ER 240mg capsule 00378-5340-01	176%	$36.46	$19.65	$16.81	86%
7	Phenytoin Sodium ER 100mg 00378-1560-10	61.9%	$17.77	$16.29	$1.48	9%
8	Temazepam 15mg capsule 00378-4010-01	1230%	$43.44	$10.35	$33.09	320%
9	Temazepam 30mg capsule 00378-5050-01	1156%	$50.05	$11.09	$38.96	351%
10	Acyclovir 800mg tablet 00378-0302-01 (subject to a FUL)	1496%	$79.88	$23.06	$56.82	246%
11	Lorazepam 1mg tablet 00378-0457-01 (subject to a FUL)	675%	$43.60	$14.04	$29.86	213%
12	Lorazepam 2mg tablet 00378-0777-01 (subject to a FUL)	723%	$63.26	$16.58	$46.68	282%
13	Piroxicam 20mg capsule 00378-2020-01	7685%	$154.23	$9.24	$144.99	1568%

(Declaration of Suzanne Graydon ("Graydon") Decl. ¶ 5 and Ex. 1, attached thereto.)

Further, contrary to Mylan's argument, the findings of the Myers and Stauffer reports do not support Mylan's position that the reimbursement rate that California adopted in 2004 continued to result in dollar margins comparable to the levels of 2000. They did not. (CA SOAF Mylan ¶ 2.)

#	Drug	"Spread" Between Published AWP and Average Actual Acquisition Cost	Actual Medi-Cal Reimbursement Amount per claim (2004)	Provider's Cost	Provider's Dollar Margin or Loss	Provider's Margin or Loss Percent
14	Temazepam 15mg capsule 00378-4010-01	1230%	$15.44	$10.35	$5.09	49%
15	Temazepam 30mg capsule 00378-5050-01	1156%	$17.74	$11.09	$6.65	60%
16	Acyclovir 800mg tablet 00378-0302-01 (subject to a FUL)	1496%	$59.45	$23.06	$36.39	158%
17	Lorazepam 1mg tablet 00378-0457-01 (subject to a FUL)	675%	$41.56	$14.04	$27.52	196%
18	Lorazepam 2mg tablet 00378-0777-01 (subject to a FUL)	723%	$41.44	$16.58	$24.87	150%
19	Piroxicam 20mg capsule 00378-2020-01	7685%	$14.04	$9.24	$4.80	52%

(Graydon Decl. ¶ 7 and Ex. 1, attached thereto.)

As these figures demonstrate, Mylan apparently picked a single NDC which it believed supported its argument. However, a comparison with other NDCs reveals that the reimbursement rate that California adopted in 2004 actually resulted in different dollar margins and cannot be said to be comparable to the levels of 2000.

It is illogical for Mylan to conclude that, based on dollar margins for seven NDCs for one particular year and an apparently unchanged profit margin for one NDC between 2000 and 2004, California must have knowingly endorsed Defendants' reporting of grossly inflated AWPs and causing Medi-Cal to reimburse pharmacists in excessive amounts.

Mylan's assertion that the payments Medi-Cal made for Mylan's drugs both before and after September 2004 were consistent with the goals of efficiency, economy, and access to quality care, is not a reasonable conclusion that can be drawn from this evidence -- let alone, as Mylan argues, "the only conclusion." Accordingly, Mylan's motion for partial summary judgment on these grounds must also be denied.

III. OTHER GROUNDS

A. None of Plaintiffs' Claims in the Present Action Are Barred by the R*es Judicata* Effect of the Prior Antitrust Action.

Notwithstanding this Court's ruling in *Massachusetts v. Mylan Labs*., No 03-11865-PBS, 2009 US Dist. LEXIS 20332, (D. Mass. March 11, 2009), Mylan has brought this summary judgment motion on the same facts and theory. Just as this Court denied its motion in the Massachusetts action, it should deny its motion here.

Mylan argues that the Plaintiffs are barred by the *res judicata* effect of California's 2001 antitrust settlement. In order to be entitled to summary judgment on the basis of *res judicata*, Mylan bears the burden of showing that the facts which underlie Plaintiffs' claims arise from the same common nucleus of operative facts as those claims that were settled in the Lorazepam/Clorazepate action ("Antitrust Case."). *See e.g., Apparel Art Int'l, Inc. v. Amertex Enter., Ltd. ("Apparel Art")*, 48 F.3d 576, 583 (1st Cir. 1995).[5] *Res judicata* is an affirmative defense on which the defendant has the burden to set forth facts sufficient to satisfy the elements. *In re Sonus Networks, Inc., Shareholder Derivative Litigation*, 499 F.3d 47, 56 (1st Cir. 2007); *Davignon v. Clemmey*, 322 F.3d 1, 17 (1st Cir. 2003).

The First Circuit has adopted the "transactional" approach of the RESTATEMENT (SECOND) OF JUDGMENTS section 24 in determining whether the defendant has met its burden. *See Manego v. Orleans Bd. of Trade ("Manego")*, 773 F.2d 1, 5 (1st Cir. 1985). The transactional approach holds that a valid and final judgment will extinguish subsequent claims "'with respect to all or any part of the transaction, or series of connected transactions, out of which the action arose.'" (*Mangego* at 5 (quoting RESTATEMENT § 24); *accord, Porn v. National*

[5] Federal law principles of *res judicata* govern this case. *See Apparel Art Int'l, Inc. v. Amertex Enter. Ltd.*, 48 F.3d 576, 583 n. 7 (1st Cir. 1995).

Grange Mut. Ins. Co., 93 F.3d 31, 34 (1st Cir. 1996). The court determines what factual grouping constitutes a "transaction" pragmatically by giving weight to such factors as "'whether the facts are related in time, space, origin, or motivation, whether they form a convenient trial unit, and whether their treatment as a unit conforms to the parties' expectations'" or business understanding or usage. *Id. (*quoting RESTATEMENT § 24 and citing *Aunyx Corp. v. Canon U.S.A., Inc*., 978 F.2d 3, 7 (1st Cir .1992). Accordingly, Mylan must satisfy several factors: (1) that the facts are related in time, space, origin or motivation, (2) that the facts form a convenient trial unit, and (3) that treating the facts as a unit conforms to the parties' expectations. *See Apparel Art*, 48 F.3d at 583.

Mylan has not established that the facts related to California's claims in the present case are remotely similar to the facts alleged in the Antitrust Case. Even a cursory comparison demonstrates that they are not.

In the Antitrust Case, the Federal Trade Commission and several states sued Mylan Laboratories, Inc. and four other defendants under a conspiracy theory, alleging that Mylan conspired to obtain exclusive licenses with lorazepam and clorazepate API suppliers that barred other drug manufacturers' access to the lorazepam and clorazepate API, the most significant ingredient in manufacturing tablets of the two drugs. By essentially controlling the only means to produce lorazepam and clorazepate in the United States, Mylan created a monopoly in the industry and manipulated the market by blocking any potential competition which resulted in an unreasonable restraint of trade. (CA Resp. Mylan SOF ¶¶ 1-3.) In the Complaint ("Joint Antitrust Complaint") the plaintiff states alleged that Mylan had violated: (1) section 2 of the Sherman Act by acting with specific intent to monopolize, and destroy competition in the generic lorazepam and clorazepate tablets market, and by entering into agreements and profit sharing

arrangements through exclusive licenses to buy lorazepam and clorazepate API (Joint Antitrust Complaint, Count XIII); (2) section 1 of the Sherman Act because Mylan's exclusive licensing agreement unreasonably restricted competition and constituted an unreasonable restraint of trade (Joint Antitrust Complaint, Count XV); (3) section 2 of the Sherman Act because Mylan obtained monopoly power in the generic lorazepam and clorazepate tablets market (Joint Antitrust Complaint, Count XVII); (4) section 2 of the Sherman Act because Mylan acted with specific intent to monopolize, and to destroy competition in, the generic lorazepam and clorazepate tablets market and willfully engaged in a course of exclusionary conduct in order to obtain a monopoly in the generic lorazepam and clorazepate tablets market (Joint Antitrust Complaint, Count XVIII); (5) section 1 of the Sherman Act because Mylan conspired to fix, raise, or stabilize the prices of lorazepam and clorazepate API (Joint Antitrust Complaint, Count XXI); and (6) California's consumer protection statute and California's antitrust statute. (Joint Antitrust Complaint, Count XXII). The transactions in the Antitrust Case involved Mylan's attempts to control the supply of the API for lorazepam and clorazepate and Mylan's actions and agreements with its co-defendants (and API suppliers and brokers) Cambrex Corporation, Profarmaco S.r.1, Gyma Laboratories of America, Inc. and SST Corporation. (CA Resp. Mylan SOF ¶¶ 4-15.)

The present case has nothing to do with manipulation of the market for the API for lorazepam and clorazepate or Mylan's actions with Cambrex, Profarmaco, Gyma or SST. Rather, the gist of Plaintiffs' claims in this action is that Mylan reported false and inflated AWP prices to First DataBank, which were used by Medi-Cal to reimburse pharmacies for the subject drugs. (CA Resp. Mylan SOF ¶ 34.) To prove its claims in the current action, Plaintiffs are not required to prove any element of any offense alleged in the Antitrust Case.

Not only are the elements of the two cases entirely distinguishable, but the same evidence will not sustain both actions. *See Scarfo v. Cabletron Systems, Inc.*, 54 F.3d 931 (1st Cir. 1995); *Minarik Elec. Co. v. Electro Sales Co., Inc.*, 223 F. Supp. 2d 334, 337 (D. Mass. 2002). Therefore, the Final Judgment in the Antitrust Case is no bar to litigating the present causes of action.

B. None of Plaintiffs' Claims in the Present Action are Barred by the Limited Release in the 2001 Settlement of the Antitrust Case.

1. The Antitrust Case's Settlement Agreement and Release Should Be Narrowly Interpreted According to its Plain Meaning.

The Settlement Agreement and Release in the Antitrust Case are governed by New York law.[6] According to New York law, a release is narrowly construed so as to give full effect to any stated limitations. *Dury v. Dunadee*, 383 N.Y.S.2d 748, 750 (App. Div. 1976) (ruling that "in interpreting a release, 'general words of release are limited by a recital of a particular claim") (quoting *Topat Equip. Co. v. Porter*, 377 N.Y.S.2d 339 (App. Div. 1975) ("[I]f, from the recitals therein or otherwise, it appears that the release is to be limited to only particular claims, demands, or obligations, the instrument will be operative as to those matters alone, and will not release other claims, demands or obligations' (citations omitted))." *See Scholastic, Inc. v. Harris*, 259 F.3d 73, 82 (2d Cir. 2001) (courts must narrowly construe the language of a release according to its plain meaning).

Moreover, under New York law, principles of contract law generally govern the interpretation of release agreements. *Consolidated Edison v. Northeast Utilities*, 332 F. Supp. 2d 639, 646 (S.D.N.Y. 2004). When interpreting an unambiguous contract, words and phrases are given their plain meaning. *Scholastic,* 259 F.3d at 82; *Krumme v. Westpoint Systems, Inc.,* 238

[6] The parties agreed that the Settlement Agreement "shall be governed by, and construed in accordance with the laws of the state of New York." (CA Resp. Mylan SOF ¶ 22.)

F.3d 133, 139 (2d Cir. 2000); *see also Around the Clock Delicatessen, Inc. v. Larkin*, 648 N.Y.S.2d 678 (App. Div. 1996).

Under New York law, releases are to be interpreted to give effect to the intent of the parties, which should be ascertained from the plain language of the agreement. 19A N.Y. Jur, Compromise, Accord, and Release, § 86; *Golden Pac. Bancorp. v. Fed. Deposit Ins. Corp.*, 273 F.3d 509, 515 (2d Cir. 2001); *Nat'l Helicopter Corp. of Am. v. City of New York*, 137 F.3d 81, 87 (2d Cir. 1998) ; see also *Hughes v. Long Island Univ.*, 762 N.Y.S.2d 401, 401 (App. Div. 2003) (limiting release specifically limited to civil rights action and did not preclude later state court personal injury claim); *Zilinskas v. Westinghouse Elec. Corp.*, 669 N.Y.S.2d 703, 704-05 (App. Div. 1998) (disputed claim not subject to release because it did not literally fall within the scope of the release language, not because the release failed to specifically refer to the disputed claim); *Dillon v. Dean*, 653 N.Y.S.2d 639 (App. Div. 1997) (ruling that release did not cover additional claims when release expressly stated particular claims being settled).

2. The Release In the Antitrust Case Is Narrowly Drawn and Does Not Release the Claims at Issue in This Case.

Mylan's argument that the Release in the Antitrust Case releases it from liability in the present case is without merit. The Release in the Antitrust Case defines the claims being released as:

> [A]ll claims…and causes of action arising under federal or state antitrust, unfair methods of competition or consumer protection laws, under state or federal unfair or deceptive trade practices acts, or under common law, asserted or that could have been asserted…by the Plaintiff States on behalf of state agencies…arising from the facts, matters, transactions, events, occurrences, acts, disclosures, statements, omissions, or failures to act set forth or alleged in the [Joint Third Amended Complaint]…

(CA Resp. Mylan SOF ¶ 19.)

While it is true that the Release applies to statutory causes of action under state "antitrust, unfair methods of competition, [and] consumer protection laws," as well as state "unfair or deceptive trade practices acts," there is no way to construe this Release as applying to a cause of action under the CA FCA. (CA Resp. Mylan SOF ¶¶ 21, 29-31.) This statute is simply not an "antitrust, unfair methods of competition or consumer protection law" or an "unfair or deceptive trade practices act": it is a false claims act, designed to protect the public fisc, including particularly the funds appropriated for the Medicaid program.

Mylan's release argument fails for a second reason. By the express terms of the Settlement Agreement, the only state statutory claims released are those "arising from the facts … set forth or alleged in the [Joint Third Amended Complaint.]" (CA Resp. Mylan SOF ¶¶ 21, 29-31.) California could not have alleged a violation of the CA FCA based on the "facts set forth or alleged in the [Joint Third Amended Complaint]."

C. Mylan Laboratories Inc. is a Proper Party in This Lawsuit.

Finally, Mylan argues that Mylan, Inc., formerly known as Mylan Laboratories, Inc., is not a proper party in this lawsuit because it is a holding company and did not manufacture, market, or sell any of the Mylan drugs at issue in this case.[7] It argues that its wholly owned subsidiary, Mylan Pharmaceuticals, Inc., manufactured, marketed and sold the drugs at issue, and should be the only named Mylan entity defendant.

However, there is a genuine issue of material fact as to whether Mylan Laboratories, Inc. (Mylan Inc.) manufactured, marketed and sold the drugs at issues in this case during the relevant time period. (CA Resp. Mylan SOF ¶¶ 35-37.) Mylan Laboratories, Inc.'s Form 10-K, filed with the Securities and Exchange Commission ("SEC") for the fiscal year which ended March 31,

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[7] In addition to Mylan Pharmaceuticals, Inc., Plaintiffs named Mylan Laboratories, Inc. as a defendant in this action. Thereafter, the name Mylan Laboratories, Inc. was changed to Mylan, Inc. (CA Resp. Mylan SOF ¶ 36.)

2003, states "Mylan Laboratories, Inc. ("We" "the Company" or "Mylan") is engaged in developing, licensing, manufacturing, marketing and distributing generic and branded pharmaceutical products." (CA Resp. Mylan SOF ¶ 37.) It also states "[W]e," defined as Mylan Laboratories, Inc., "manufacture and market approximately 115 generic pharmaceuticals in capsule or tablet form in an aggregate of approximately 285 dosage strengths. (*Id.*) These statements directly contradict Mylan's assertion in its Summary Judgment Motion that it does not manufacture, market or sell pharmaceuticals and create a genuine issue of material fact for trial.

The entire thrust of Mylan's 2003 SEC Form 10-K is that Mylan is a single business entity which is operated and controlled by Mylan Laboratories, Inc. (CA Resp. Mylan SOF ¶ 37.) In that document Mylan Laboratories, Inc. is defined as "We." (*Id.*) Mylan makes the statements that "[w]e conduct business through our generic…pharmaceutical operating segment[]" and "[w]e are recognized as a leader in the generic pharmaceutical industry." (*Id.*) It refers to Mylan Pharmaceuticals, Inc., its wholly owned subsidiary, as its "primary generic pharmaceutical…division." (*Id.*) It also states that "[i]n fiscal 2003, Mylan [defined as Mylan Laboratories, Inc.] held the first or second market position in new and refilled prescriptions dispensed among all pharmaceutical companies in the U.S. with respect to 96 of the 133 generic pharmaceutical products we marketed, excluding unit-dose products." (*Id.*) All of these statements support the assertion that Mylan Laboratories, Inc. (Mylan, Inc.) manufactured, marketed and sold pharmaceuticals during the relevant time period and is a proper defendant in this case.

Mylan designated Brian Roman as a Rule 30(b)(6) deposition witness. Mr. Roman testified as to his role as Associate General Counsel of Operations for Mylan Laboratories, Inc.

(Mylan, Inc.) and as Vice President and General Counsel at Mylan Pharmaceuticals Inc. (CA Resp. Mylan SOF ¶ 38.) Rod Jackson, a Senior Vice President of Mylan Laboratories, Inc., has testified to his role in the 1998 lorazepam price changes. (CA Resp. Mylan SOF ¶ 38.) Organizational charts produced by Mylan in this case confirm that Mr. Jackson was an officer of Mylan Laboratories, Inc. and that officials of Mylan Pharmaceuticals, Inc. reported to him. (CA Resp. Mylan SOF ¶ 38.) This evidence supports the conclusion that Mylan Laboratories, Inc. (Mylan, Inc.) controlled the marketing and sales of the Mylan drugs at issue in this case and is a proper defendant.

IV. CONCLUSION

For the foregoing reasons, Mylan has failed to carry its burden of showing that there are no genuine issues of material fact for trial and that it is entitled to summary judgment as to any of Plaintiffs' claims. As a result, Mylan's Motion for Partial Summary Judgment should be denied in its entirety.

Dated: December 21, 2009

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that a true and correct copy of the foregoing was delivered to all counsel of record by electronic service pursuant to Paragraph 11 of the Case Management Order No. 2, by sending on December 21, 2009, a copy to Lexis-Nexis for posting and notification to all parties.

/s/ *Matthew C. Kilman*
MATTHEW C. KILMAN